SECTION 6. 510(K) SUMMARY

AUG - 4 2011

Submitter:	Syncro Medical Innovations, Inc. 20 West Federal Suite M-5B Youngstown, OH 44503
Submission Correspondent:	William G. McLain President and Principal Consultant Keystone Regulatory Services, LLC. Phone: 717-656-9656 Fax: 717-656-3434 Email: bill.mclain@keystoneregualtory.com
Date summary prepared:	December 31, 2010
Device trade name:	Syncro-Blue Tube, The Magnetically Guided Enteral Feeding Tube
Device common name:	Feeding Tube
Device classification name:	Tube, Feeding 78 KNT at 21 CFR Part 876.5980
Legally marketed devices to which the device is substantially equivalent:	Gabriel Blue Tube Magnetically Guided Enteral Feeding Tube cleared under K072787
Description of the device:	The Syncro-Blue Tube serves as a conduit through which enteral feeding solutions are directly infused into the patient's small bowel. The modified device will be marketed in one length (23.6" [60cm]) and one French size (8 Fr). During placement of the tube, an external magnet is used to assist the physician in placing the tube into the small bowel. The Syncro-Blue Tube has a stylet with a reed switch positioned near its distal tip. The reed switch is connected by wires to an external LED/battery pack that lights in response to the presence of the external steering magnet. The reed switch is located at the distal end of the stylet. The distal tip of the stylet contain magnets which are attracted to the steering magnet. When the tube is positioned, the stylet is removed from the device, making the Syncro-Blue Tube MRI Safe.
Intended use of the device:	The Syncro-Blue Tube™ functions as a conduit to facilitate enteral feeding, and may be used in the pediatric, adult or elderly patient who cannot consume an adequate diet orally. Small bowel feeding may be indicated for patients with functioning gut who require short- to moderate-term feeding support, such as post-trauma patients, post-surgical patients, burn patients, general trauma patients, high-risk patients prone to tube misplacement complications, and patients in whom malnutrition exists, or may result, secondary to an underlying disease or condition. The external steering magnet functions as a guidance tool to assist in the safe, rapid placement of the feeding tube into the small bowel.

Technological characteristics:	The proposed device has the same technological characteristics as the predicate device(s).
Performance tests:	Tests were performed to demonstrate substantial equivalence in the following areas: • Tensile • Aspiration, Flow • Magnet Capture / Magnetic guidance • Flexibility / Column Strength / Pushability • Biocompatibility • Simulated use. • Radiopacity • LED Turn-on Distance • Connector Compatibility Testing
Conclusions:	The results of the laboratory tests demonstrate that the device is as safe and effective as the legally marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Syncro Medical Innovations, Inc.
% William G. McLain, RAC
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AUG - 4 2011

Re: K110005
Trade/Device Name: Syncro-Blue Tube Magnetically Guided Enteral Feeding Tube
Regulation Number: 21 CFR §876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: II
Product Code: KNT
Dated: July 2, 2011
Received: July 5, 2011

Dear Mr. McLain:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. *Please note:* If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner, M.D., Director (Acting)
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

SECTION 7. INDICATIONS FOR USE STATEMENT

510(k) Number: K110005

Device Name: Syncro-Blue Tube Magnetically Guided Enteral Feeding Tube

Indications for Use: The Syncro-Blue Tube™ functions as a conduit to facilitate enteral feeding, and may be used in the pediatric, adult or elderly patient who cannot consume an adequate diet orally. Small bowel feeding may be indicated for patients with functioning gut who require short- to moderate-term feeding support, such as post-trauma patients, post-surgical patients, burn patients, general trauma patients, high-risk patients prone to tube misplacement complications, and patients in whom malnutrition exists, or may result, secondary to an underlying disease or condition.

Prescription Use √ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K110005